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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,644	03/15/2002	Susan A. Gregory	C2916/4 (PHA 4151.7)	7986

321 7590 08/26/2003

SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/26/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/098,644

Applicant(s)

GREGORY ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

This application was filed 15 March 2002 and is a DIV of 09/430072 (filed 10-18-1999, now US Patent #5,376,528) which is a CON of 09/189,463 (filed 11-10-1998, ABN) which is a CON of 08/600,622 (filed 2-13-1996, ABN). Claims 9-20 are before the Examiner.

#### *Claim Rejections - 35 USC § 102/103*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9-20 remain rejected under 35 U.S.C. 102(b/e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Isakson (US Patent #6,136,839), Gregory (US Patent #6,407,140), WO 96/41626, and Engelhardt (CA 125:292089) and now further in view of Talley (US Patent #5,859,257), Hagmann (US Patent #4,919,776), Isakson (US Patent #5,990,148), Mills (US Patent #6,013,644) and Finke (US Patent #6,500,844), for the reasons cited in paper #5, dated 11 February 2003.

Applicant argues in paper #8, dated 11 June 2003, that the cited art does not teach a combination of COX-2 inhibitor, a 5-LO inhibitor and an immunosuppressive drug as required by claim 9. However, claim 9 requires a combination of COX-2 inhibitor, a 5-LO inhibitor and an immunosuppressive drug selected from antiproliferation agents, anti-inflammatory-acting compounds and inhibitors of leukocyte activation. Cyclosporin is an immunosuppressive drug that inhibits leukocyte activation (see Gregroy col 2 paragraph of line 16-49). This fits within the teaching of Engelhard which teaches COX-2 inhibitors, leukocyte inhibitors and 5-lipoxygenase inhibitors. Applicant states on page 18, second paragraph that Hagmann discloses aminoquinolines that modulate chemokine receptor activity and are used to treat inflammatory and immunoregulatory disorders. Isakson discloses the combination of COX-2, 5-LO and anti-inflammatory compounds. Combining Isakson and Hagmann, the combination of the instant claims becomes obvious (using Hagmann) or anticipatory (using the combination taught by Isakson).

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is seen as not enabling for the instant claims because the claims are drawn to a composition containing several active ingredients. The specification does not provide any guidance with respect to how to make the compounds. One of ordinary skill in the art would have to find a compound, determine what activity it may have, and then put it into a composition with other active ingredients that have yet to be determined. The only identification for identifying characteristics for recognizing that a compound is a candidate for the instant claims is the activity. That activity must be determined and then the possible compounds must be mixed with other active compounds. The selection of compounds is not enabled by the instant specification.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms